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09/938,497	08/27/2001	Maria K. Boden Wastfelt	012889-086	3731

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/938,497

Applicant(s)

BODEN WASTFELT ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 10,11,14-17,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12,13,18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

The Final Office Action of Paper 13 (mailed 10/6/03) has been vacated in view of the present Final Office Action. A Supplemental Response was filed by Applicants on 9/24/03. Since this Amendment was received by the Office prior to the mailing of the Office Action of 10/6/03, Applicants are entitled to a new Office Action on the Merits.

#### ***1. Formal Matters***

- A. Amendment D, filed 9/24/03, has been entered into the record.
- B. Amendment C, filed 8/7/03, has been entered into the record.
- C. Amendment B, filed 6/12/03, has been entered into the record.
- D. Claims 2-7 and 9-13 were pending in this Office Action. Claims 1-9 have been cancelled and claims 10-11 have been withdrawn as being drawn to non-elected subject matter. Therefore, claims 10-21 are pending. Claims 12, 13, 18 and 19 are the subject of this Office Action.
- E. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

#### ***2. Election by Original Presentation***

- A. Applicants have added new claims 14-21. Newly submitted claims 14-17 are restricted into original Group II of the Office Action mailed 12/18/02. New claims 20 and 21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected protein (pending claims 12 and 13) and the method of claims 20 and 21 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 14-17, 20 and 21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. However, method claims that are commensurate in scope with the originally elected invention will be rejoined if the claims to said

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invention are found allowable and the rejoined claims do not contain any issues under 35 USC 112. This original restriction is made **FINAL**.

**3. Oath/Declaration**

A. The objection to the Declaration has been withdrawn in view of Applicants submission of a new Declaration with initialed changes.

**4. Specification**

A. The specification is objected to since the sequences on page 11, lines 27-35 and page 12, lines 4-6 need sequence identifiers. See 37 CFR 1.821-1.825. If new SEQ ID NOs are added, then Applicants are required to submit a new sequence listing and disk, as well as a statement that both the disk and sequence listing are identical and contain no new matter.

**5. Claim Objections**

A. Claims 12, 13, 18 and 19 are objected to since claim 12 recites "derived from." The syntax could be improved by replacing this phrase with, for example, "obtained from" or "isolated from." Claims 13, 18 and 19 are objected to since they depend from claim 12.

B. Claim 19 is objected to since it depends from itself. It is believed that this claim should depend from claim 18.

**6. Claim Rejections - 35 USC § 112, first paragraph – enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed fibrinogen binding protein for use in inhibiting Staph binding to fibrinogen in mammals, does not reasonably provide enablement for compositions comprising this protein and a pharmaceutical carrier for the treatment of other conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming a composition in a pharmaceutical carrier for treating any and all diseases. This claim is an 'intended use' of the protein of the invention. Applicants provide no guidance or working examples of any diseases which can be treated by using the Staph binding protein of the invention other than to inhibit Staph binding to fibrinogen. Nor is it predictable to one of ordinary skill in the art what other conditions can be treated. These factors lead the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

***7. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a genus claim. The claim is an 'intended use' claim regarding 'pharmaceutical carrier.' The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus of diseases to be treated by the claimed protein other than to inhibit Staph binding to fibrinogen. Thus the scope of the claims includes numerous diseases, and the genus is highly variant because a significant number of diseases is permitted. The specification and claims do not provide any guidance as to what other disease can be treated by the claimed protein. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "inhibition of Staph binding to fibrinogen" alone is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

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**8. Claim Rejections - 35 USC § 102**

A. The rejection of claim 12 and 13 under 35 USC 102(b) as being anticipated by Palma et al. has been withdrawn in view of Applicants' argument that the present invention receives priority at least to PCT/SE93/00759. The effective U.S. filing date is 5/23/94. Applicants have amended the first line of the specification to reflect this priority. Therefore, the present invention deserves priority prior to the 1998 publication date of Palma et al.

B. Claims 12 and 13 remain rejected and new claims 18 and 19 are also rejected under 35 USC 102(b) as being anticipated by Boden et al. Applicants argue that the present invention deserves priority as far back as its Swedish application 9202720-0, filed 9/21/92. However, the present application is a CON of PCT/SE93/00759 and is not the National Stage entry. Therefore, the effective U.S. filing date of the present application is 5/23/94, the filing date of U.S. Application 08/244,229. The Boden et al. reference was published 4/92, more than 1 year prior to the effective U.S. filing date and is, therefore, considered prior art under 35 USC 102(b).

**9. Conclusion**

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
January 21, 2004

  
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